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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/836,804      | 04/17/2001  | Gebre-mariam Mesfin  | 6267.N              | 6782             |

7590

07/02/2002

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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/836,804

Applicant(s)

MESFIN ET AL.

Examiner

Shaojia A. Jiang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This Office Action is a response to Applicant's amendment and response filed on April 8, 2002 in Paper No. 7 wherein claim 13 is cancelled. Currently, claims 1-12 are pending in this application.

Applicant's amendment (canceling claim 13) filed April 8, 2002 in Paper No. 7 with respect to the rejections made under 35 U.S.C. 112 second paragraph and under 35 U.S.C. 101 for the claimed recitation of a use in claim 13 has been fully considered and found persuasive to remove the rejection. Therefore, the said rejection is withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hester et al. (WO 9854161) in view of Nair et al. for reasons of record stated in the Office Action dated October 24, 2001.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (WO 9912914) in view of Nair et al. for reasons of record stated in the Office Action dated October 24, 2001.

Applicant's remarks filed on April 8, 2002 in Paper No. 7 with respect to the rejection of claims 1-13 made under 35 U.S.C. 103(a) as being unpatentable over Hester et al. (WO 9854161) in view of Nair et al. and the rejection of 1-13 made under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (WO 9912914) in view of Nair et al., in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant asserts that Nair et al. does not teach, suggest, or conclude that antibacterial agents would be useful in the treatment of bone diseases herein. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 SPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

In the instant case, Hester's method or Yoshida's method inherently treats or protects osteoporosis, bone resorption, or other bone disease in a vertebrate mammal, as claimed herein since Hester's method steps or Yoshida's method steps are same as the instant method steps. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency as it related to the claimed invention herein.

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Applicant further asserts that one of embodiments of Applicant's invention is the treatment of bone diseases where no bacterial infection is present (see claim 6).

However, the instant base claims and other dependent claims, 1-5 and 7-11, read on the treatment of any osteoporosis, bone resorption, or other bone disease in a vertebrate mammal, including the bone diseases associated with bacteria.

Therefore, motivation to combine the teachings of the prior art cited herein to make the present invention is seen. The claimed invention is clearly obvious in view of the prior art.

Applicant's results on "Use of Compounds" of the specification at pages 44-45 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive for the reasons below. The example of "Use of Compounds" herein provides no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art. Moreover, there is no comparison with the prior art. Further, the example herein merely demonstrate the employment of one particular compound within the instant claims in the treatment for increasing bone mass and density. Thus, the evidence in the example is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the active compounds in the claimed methods of treating various bone diseases herein. See MPEP § 716.02(d). Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejections are adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.  
Patent Examiner, AU 1617  
June 17, 2002

RUSSELL TRAYERS  
PRIMARY EXAMINER  
GROUP 1200